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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/674,290   | 09/29/2003  | Gregory A. Demopulos | PH.1.0006.US2       | 3124             |
| 31629  | 7590        | 12/13/2005           | EXAMINER            |                  |
| OMEROS MEDICAL SYSTEMS, INC.<br>1420 FIFTH AVENUE<br>SUITE 2675<br>SEATTLE, WA 98101 |             |                      | KWON, BRIAN YONG S  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1614                |                  |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 40-64, drawn to a pharmaceutical product.
- II. Claims 1-39, drawn to a process of using said product.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product (i.e., embolism, thrombosis, diabetes, autoimmune disease, etc...).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. If the applicant elects Group I invention, the elected invention is subject to further restriction as following.

I(a). Claims 40-44, 51-55 and 62-64, drawn to a pharmaceutical solution comprising a plurality of restenosis inhibitor agent.

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- I(b). Claims 40-47, 51-58 and 62-64, drawn to a pharmaceutical solution comprising restenosis inhibitors in combination with spasm inhibitory agent.
- I(c). Claims 40-44, 48-55 and 59-64, drawn to a pharmaceutical solution comprising restenosis inhibitors in combination with pain/inflammation inhibitor agents.
- I(d). Claims 40-50, drawn to a pharmaceutical solution comprising restenosis inhibitors in combination with pain/inflammation inhibitor agents and spasm inhibitory agent.

One practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent. Thus, restriction for examination purposes as indicated is proper.

3. If the applicant elects Group II invention, the elected invention is subject to further restriction as following.

- II(a). Claims 1-14 and 21-39, drawn to a process of inhibiting restenosis in a vascular procedure comprising administering restenosis inhibitor agents.
- II(b). Claims 1-17 and 21-23, drawn to a process of inhibiting restenosis and selectively inhibiting spasm in a vascular procedure comprising administering restenosis inhibitors in combination with spasm inhibitory agents.

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- II(c). Claims 1-14, 18-20 and 21-23, drawn to a process of inhibiting restenosis and selectively pain/inflammation in a vascular procedure comprising administering restenosis inhibitors in combination with pain/inflammatory inhibitory agent.
- II(d). Claims 1-23, drawn to a process of inhibiting restenosis and selectively pain/inflammation and spasm in a vascular procedure comprising administering restenosis inhibitors in combination with pain/inflammatory inhibitory agent and spasm inhibitory agents.

One practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent. Thus, restriction for examination purposes as indicated is proper.

4. In addition, applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g., the specific compound from (i) "restenosis inhibitor agent", (ii) "spasm inhibitor agent" or (iii) "pain/inflammation inhibitory agent" exemplified in page 62-84 of the instant specification) under the instant claims of the elected Group. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon.

With the election of a specific exemplified compound, a generic concept will be identified by the examiner as the inventive group for examination.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon  
Patent Examiner  
AU 1614

A handwritten signature in black ink, appearing to be 'BK', followed by a long horizontal line.